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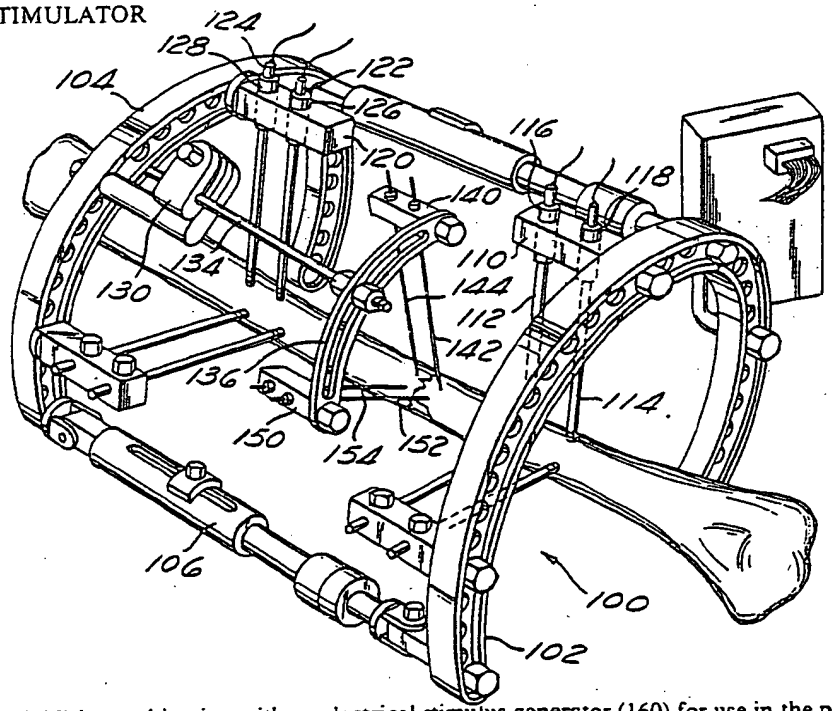

(57) Abstract

An external fixation device (100) in combination with an electrical stimulus generator (160) for use in the promotion of osteosynthesis in the healing of a bone fracture. Implemented as follows: using a standard external fixation device (160); fix the site of the bone fracture by inserting a first and second pair of fixation pins (112, 114, 122, 124) on each side of the fracture site; fixing at least one cathode (142) in electrical contact with the bone adjacent to the fracture site; and the cyclically applying a voltage between the fixation pins (112, 114, 122, 124) and the cathode (142). Whereby, current flows in a defined cycle from cathode (142) to one of the two pairs of fixation pins (112, 114, 122, 124), then from one pair of pins to the other, then from the cathode (142) to the other pair of electrodes.

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BONE GROWTH STIMULATOR

Field of the Invention.

This invention relates to orthopedic surgery and, more specifically, to external fixation and bone growth stimulation apparatus.

Background of the Invention.

It has been known for three decades that bone structures have bioelectric properties. It is known, for example, that bones tend to be electronegative in areas of compression and electropositive in areas of tension, and that areas of active growth and repair tend to be electronegative. Many workers have demonstrated the phenomenon of electric current stimulated osteogenesis at the cathode. Electric currents, both AC and DC, including pulsating DC, in the range of from about 10 to 100 microamperes is known to stimulate bone growth in some but not necessarily all subjects. The literature on this subject is extensive, see, e.g. Spadaro JA: Electrically Stimulated Bone Growth in Animals and Man, A review of the Literature, Clin. Orthop. 122:325, 1977.

Implantable electric current bone growth stimulator devices have been reported, see, e.g., U.S. Patents Nos. 3,745,995; 3,783,880; 3,890,953; 3,915,151; 3,968,790; 4,011,861; 4,052,754; 4,306,564; 4,313,438; 4,315,503; 4,333,469 and 4,414,979. Prostheses having electrically stimulated bone growth devices have also been proposed; see, e.g., U.S. Patents Nos. 3,964,473; 4,195,367; 4,214,322 and 4,216,548. Non-invasive bone growth stimulators, see, e.g. U.S. Patents Nos. 4,056,097; 4,066,065; 4,153,060; 4,175,565 and 4,244,373, and bone growth stimulators with specific current and voltage patterns, see, e.g., U.S. Patents Nos.

4,105,017; 4,266,532; 4,266,533; and 4,315,503, have been described. Semi-invasive bone growth stimulators have also been disclosed, see, e.g., Zimmer, "The Alternate Treatment of Fracture Nonunion, Electrical Stimulation to Induce Osteogenesis, Zimmer USA, Warsaw, Indiana 46580, September 1979 revision, and U.S. Patents Nos. 3,842,841 and 3,918,440.

U.S. Patent No. 4,026,304 reviews the state of the art and early developments and is incorporated herein by reference. This patent also discusses the problem of polarization and proposes, as a solution, an implantable source of electric potential to generate a train of electric pulses.

U.S. Patent No. 3,893,462 discloses another method of bone growth stimulation utilizing electrical signals undulating in both the positive and negative directions in an asymmetric manner reactively coupled to the bone.

The general approach in the prior art has been to provide an electric current bone growth stimulator separately from any external fixation which may be used. While efforts have been made to avoid or mitigate the problem of polarization which results when current flows in a given direction through an electrode. The present invention addresses the problems of external fixation and bone growth stimulation, including the problem of polarization.

Summary of the Invention

The present invention comprises an apparatus for both fixing a bone fracture and stimulating the bone growth repair of the fracture, while eliminating or at least mitigating the effects of polorization in electric current induced osteogenesis. The present invention includes a method for accomplishing these

results. The invention may be described, in its various facets as follows:

A combined external fixation device and bone growth stimulator comprising, in combination: a first pair of fixature pins for extending into a fractured bone, one pin on each side of the fracture site of the bone; a second pair of fixature pins for extending into the fractured bone, one pin on each side of the fracture site of the bone; external fixation frame means for rigidly fixing the position of said first and second pins with the distal end thereof secured to the fractured bone and the proximal end secured proximate the frame means to thereby fix the position of the fractured bone on both sides of the fracture therein and thus fixing the position of the fracture site thereof; at least one cathode each comprising a relatively rigid electrically conductive wire externally insulated along a major central portion thereof, having a biologically compatible electrically conductive distal tip for contacting the fractured bone proximate the fracture therein; means secured to the external fixation frame means for fixing the position of said cathodes with the distal tip in electrical contact with the bone proximate the fracture site therein; means electrically isolating the cathodes and pins from each other thereby preventing electrical contact with one another through the frame means; and means for applying electrical voltage to the cathodes and the pins cyclically for a a plurality of time periods during each cycle, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage

is applied to any cathode, the voltage application being cycled to cause electron flow from a cathode to the first pins in a first period, from the first pins to the second pins during a second period, from a cathode to the second pins in third period, and from the second pins to the first pins in fourth period

Preferably the apparatus comprises at least two cathodes and the means for applying electrical voltage comprises means to cycle the application of voltage to cause electron flow from one cathode during the first period and from another cathode during the third period.

In a still more preferred embodiment, the apparatus includes four cathodes and the means for applying electrical voltage comprises: means for applying electrical voltage to the cathodes and the pins cyclically for a a plurality of time periods during each cycle, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode, the voltage application being cycled to cause electron flow from a first cathode to the first pins in a first period, from the first pins to the second pins during a second period, from the second cathode to the second pins in third period, from the second pins to the first pins in fourth period, from the third cathode to the first pins in the fifth period, from the first pins to the second pins in the sixth period, from the fourth cathode to the second pins in the seventh period, and from the second pins to the first pins in the eighth period.

The invention may also be described as a

ombined external fixation and bone growth stimulating means comprising the combination of: first and second pairs of fixation pins; at least one cathode; frame means for electrically isolating and fixing the position of the pins and cathodes, including means for fixing the first pair of pins fixed one on each side of the fracture site of a bone, the second pair of pins one on each side of said fracture site, and the cathodes proximate said fracture site; and means for applying a voltage for a first period between a cathode and the first pins, during a second period between the first and second pins, during a third period between a cathode and the second pins, and during a fourth period between the second and first pins, the cathode being negative during the first and third periods and neutral during the second and fourth periods, the first pins being negative during the second period and positive during the fourth period.

The invention also comprehends a method of treating a bone fracture comprising the steps of: fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site; fixing at least one cathode with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between a cathode and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during even numbered time periods between the pairs of pins alternately, the polarity being

reversed between said pins during alternate even numbered time periods.

In a specific method of treating a bone fracture, the invention comprises the steps of: fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site; fixing a plurality of cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between the cathodes alternately and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

The preferred method of treating a bone fracture according to this invention comprises the steps of: fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site; fixing at least four cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between the cathodes alternately and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during

even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

In an exemplary embodiment, the method of treating a bone fracture of this invention comprises the steps of: fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site; fixing at least four cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and applying a voltage cyclically during odd numbered and even numbered time periods, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode, the voltage application being cycled to cause electron flow from a first cathode to the first pins in a first period, from the first pins to the second pins during a second period, from the second cathode to the second pins in third period, from the second pins to the first pins in fourth period, from the third cathode to the first pins in the fifth period, from the first pins to the second pins in the sixth period, from the fourth cathode to the second pins in the seventh period, and from the second pins to the first pins in the eighth period.

Brief Description of the Drawings

Figure 1 is a side view of the apparatus of this invention, the frame being shown in simplified form.

Figure 2 is an end view of the apparatus of

this invention, taken along lines 2-2 in the direction of the arrows as shown in Figure 1.

Figure 3 is a very schematic view illustrating the principle of application of voltage to the cathodes and pins of Figures 1 and 2.

Description of the Preferred Embodiment.

The invention is described as applied to the Ace-Fischer (Trademark) external fixation device, which in very simplified form is shown in Figures 1 and 2; however, it is to be understood and emphasized that the invention includes and comprehends any external fixation device which is capable of fixing fixature pins and cathodes. The Ace-Fischer (Trademark) external fixation device is described in detail in U.S. Patent No. 4,308,863.

The invention includes an external fixation device 100 which may be in any configuration. In the depicted embodiment, which is merely exemplary and non-limiting, the fixation device includes a pair of semicircular frame members 102 and 104 secured in spaced relation about the fractured bone by adjustable rod means one of which is depicted at 106. Pin holders 110 and 120 are secured in any convenient manner to the frame members and fix the fixature pins 112 and 114, in holder 110, and 122 and 124, in holder 120, in position. Electrically insulating means 116 and 118 in holder 110 and means 126 and 128 in holder 120 electrically isolate the pins 112, 114, 122 and 124 from each other such that there is no electrical connection between them through the frame. Insulating means may be, for example, Teflon (Trademark) polytetrafluoroethylene or other insulative sleeves. The distal ends of the pins are screwed, or otherwise secured, in the usual manner to

the bone. One pair of pins, 112 and 122, are secured one pin on each side of the fracture site, and the other pair of pins, 114 and 124, are secured also one pin on each side of the fracture site. The pins on each side are spaced apart sufficiently to avoid electrical shorting therebetween.

A bracket 130 secures a rod 134 to the frame means such that the rod extend approximately parallel to the axis of the bone proximate the center of the frame where it supports an arcuate mounting bracket 136. Cathode mounting blocks 140 and 150 are secured to the mounting bracket 136 in a conventional way, such as by a bolt and nut arrangement. The block 140 mounts cathodes 142 and 144 preferrable by means of electrically insulative sleeves 146 and 148. In like manner, the block 150 mounts cathods 152 and 154 by means of sleeves 156 and 158.

As pointed out, the specific structures by which the pins and cathodes are mounted are of no consequence insofar as this invention is concerned so long as they perform the necessary function of mounting the pins in fixed relation with the distal ends of the pins secured to the bone to fix the fracture site of the bone and mounting the cathodes with the distal ends of the cathodes in electrical contact with the bone in the proximity of the fracture site. The tips of the pin may be in the fracture site, in the bone adjacent the fracture site or in the soft tissue adjacent the bone fracture site, all of which locations are referred to herein as being in electrical contact with the bone. The cathodes and pins are electrically isolated from each other, except, of course, throught the bone and the source of voltage which will be described, such that a voltage can be applied between any cathode and either pair of

pins and between the pairs of pins.

The means for applying a voltage is illustrated for the sole purpose of describing the manner in which the voltage is applied. It will be instantly understood that in practice solid state voltage regulators, switches, etc. will be used. Since the exact circuitry and devices for generating and applying a voltage are of no importance to the operation of the invention, so long as the voltage is applied as described, a simplified schematic representation has been selected to more clearly and simply illustrate the voltage applying means.

As shown in Figure 3, a voltage in a particular cyclical pattern to be described is applied from the voltage applying means 170. Typically, a stable battery having long term constant voltage, indicated at 170, will be used. A current regulator depicted generally at 172 will be included. This, of course, will be a solid state device rather than the functionally schematic variable resister shown. To illustrate the cyclic manner of applying voltage, a pair of wiper switches 174 and 176 driven by motor 178 are shown simply to illustrate that the voltage will be applied sequentially to a number of electrical conductors in cable 180 and thence to the pins 112, 114, 122, and 124, and the cathodes 142, 144, 152 and 154. Again, it is emphasized that solid state switching is conveniently used and that the switching shown is functionally schematic to illustrate the principle. Since solid state circuitry of the type suitable for use in the invention is well known and conventional, and since so many circuits can suitably be used is is deemed unnecessary to describe the same in detail. Reference is made to the aforecited patents for various circuits which may used or

modified for use. Reference is also made to standard electronic circuitry texts and manuals.

The operation of the voltage apply means is as follows:

In the preferred embodiment, the apparatus includes four cathodes and two sets of pins. The means for applying electrical voltage applies electrical voltage to the cathodes and the pins cyclically for a a plurality of time periods during each cycle. The cathodes at all times having either no voltage or negative voltage applied thereto. The pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode. The conductors in cable 80 are connected to the switching mechanism such that the voltage application is cycled to cause electron flow from a first cathode to the first pins in a first period, from the first pins to the second pins during a second period, from the second cathode to the second pins in third period, from the second pins to the first pins in fourth period, from the third cathode to the first pins in the fifth period, from the first pins to the second pins in the sixth period, from the fourth cathode to the second pins in the seventh period, and from the second pins to the first pins in the eighth period.

The connection of the conductors between the switching mechanism and the cathodes and pins and the operation of the switching mechanism is fully defined by the following table.

TABLE I

Time Period	Cathode Polarity 112	114	122	124	Pin Polarity 142	152	144	154
1	-	0	0	0	+	+	0	0
2	0	0	0	0	-	-	+	+
3	0	-	0	0	0	0	+	+
4	0	0	0	0	+	+	-	-
5	0	0	-	0	+	+	0	0
6	0	0	0	0	-	-	+	+
7	0	0	0	-	0	0	+	+
8	0	0	0	0	+	+	-	-

Current was controlled in the range of 5 to 20 microamperes. The full sequence of pulsing occurs at 10 Hz timed intervals. Each sequence involves eight events -- four firings (negative charging of a cathode) and four discharges of the anodes (pins). Each of these eight events requires 12.5 milliseconds. Thus, the full eight events requires 100 milliseconds and the sequence repeats itself 10 times each second.

It will, of course, be understood that the specific order of voltage application is not critical and can be altered. What is important is that the electron flow be controlled such that it is always from the cathode to one or the other of the sets of pins, when the cathodes are active, and that there be period flow between the pins opposite the direction of flow when the cathode current flows to the pins. The intensity of the current does not differ from that taught in the prior art and may typically range from about 10 microamps to 100 microamps, normally being from 10 to 20 microamps. These ranges are, of course, typical and not critical.

Discussion

Animal studies of the invention were conducted at the Cleveland Research Institute using a canine model. Torsional strength values were almost double for stimulated tibias as compared with a control series. The histological and micro-radiographic analysis demonstrated earlier evidence of cellular activity (1-2 weeks post operatively) in the stimulated groups. The 6 weeks post operative analysis showed a more dense and more mature material tibial deposit in the stimulated tibial fractures. Significantly, the incidence of pin loosening was only one-fourth as frequent in the stimulated series as in the control series. Additionally the degree of loosening was 3.5 times greater in the control series as in the stimulated series. The level of trace elements in the model was slightly higher in the stimulated series than in the control, but the difference was marginal and the levels for both groups were well within an acceptable range. It was concluded from this series that the invention was both safe and effective in promoting fracture healing in the canine model. Clinical trials are being planned and it is predicted from the animal tests that the invention will be both safe and effective in promoting human bone growth.

It will be understood that considerable variation can be made within the principle of the invention without departing therefrom, especially as regards the structure of the fixation device, the manner of producing the electric voltage for current flow, and the specific order of cycling the voltage to the cathodes and pins.

Industrial Application

This invention will find industrial

application in veteranary medicine and in orthopedic surgery.

WHAT IS CLAIMED IS:

1. A combined external fixation device and bone growth stimulator comprising, in combination:

(a) a first pair of fixature pins (112, 122) for extending into a fractured bone, one pin on each side of the fracture site of the bone;

(b) a second pair of fixature pins (114, 124) for extending into the fractured bone, one pin on each side of the fracture site of the bone;

(c) external fixation frame means (100) for rigidly fixing the position of said first and second pins with the distal end thereof secured to the fractured bone and the proximal end secured proximate the frame means to thereby fix the position of the fractured bone on both sides of the fracture therein and thus fixing the position of the fracture site thereof;

(d) at least one cathode (142, 144, 152, 154) each comprising a relatively rigid electrically conductive wire externally insulated along a major central portion thereof, having a biologically compatible electrically conductive distal tip for contacting the fractured bone proximate the fracture therein;

(f) means secured to the external fixation frame means (100) for fixing the position of said cathodes with the distal tip in electrical contact with the bone proximate the fracture site therein;

(g) means electrically isolating the cathodes and pins from each other thereby preventing electrical contact with one another through the frame means; and

(h) means for applying electrical voltage to the cathodes and the pins cyclically for a a plurality of time periods during each cycle, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode, the voltage application being cycled to cause electron flow from a cathode to the first pins in a first period, from the first pins to the second pins during a second period, from a cathode to the second pins in third period, and from the second pins to the first pins in fourth period

2. The apparatus of Claim 1 comprising at least two cathodes and wherein the means for applying electrical voltage comprises means to cycle the application of voltage to cause electron flow from one cathode during the first period and from another cathode during the third period.

3. The apparatus of Claim 1 including four cathodes and wherein the means for applying electrical voltage comprises:

means for applying electrical voltage to the cathodes and the pins cyclically for a a plurality of time periods during each cycle, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode, the voltage application being cycled to cause

electron flow from a first cathode to the first pins in a first period, from the first pins to the second pins during a second period, from the second cathode to the second pins in third period, from the second pins to the first pins in fourth period, from the third cathode to the first pins in the fifth period, from the first pins to the second pins in the sixth period, from the fourth cathode to the second pins in the seventh period, and from the second pins to the first pins in the eighth period.

4. A combined external fixation and bone growth stimulating means comprising the combination of:

(a) first and second pairs of fixation pins;

(b) at least one cathode;

(c) frame means for electrically isolating and fixing the position of the pins and cathodes, including means for fixing the first pair of pins fixed one on each side of the fracture site of a bone, the second pair of pins one on each side of said fracture site, and the cathodes proximate said fracture site; and

(d) means for applying a voltage for a first period between a cathode and the first pins, during a second period between the first and second pins, during a third period between a cathode and the second pins, and during a fourth period between the second and first pins, the cathode being negative during the first and third periods and neutral during the second and fourth periods, the first pins being negative during the second period and positive during the fourth period.

5. A combined external fixation and bone

growth stimulating means comprising the combination of:

(a) first and second pairs of fixation pins;

(b) a plurality of cathodes;

(c) frame means for electrically isolating and fixing the position of the pins and cathodes, including means for fixing the first pair of pins fixed one on each side of the fracture site of a bone, the second pair of pins one on each side of said fracture site, and the cathodes proximate said fracture site; and

(d) means for applying a voltage for a first period between a cathode and the first pins, during a second period between the first and second pins, during a third period between another cathode and the second pins, and during a fourth period between the second and first pins, the cathode being negative during the first and third periods and neutral during the second and fourth periods, the first pins being negative during the second period and positive during the fourth period.

6. A combined external fixation and bone growth stimulating means comprising the combination of:

(a) first and second pairs of fixation pins;

(b) a plurality of cathodes;

(c) frame means for electrically isolating and fixing the position of the pins and cathodes, including means for fixing the first pair of pins fixed one on each side of the fracture site of a bone, the second pair of pins one on each side of said fracture site, and the cathodes proximate said fracture site; and

(d) means for applying a voltage cyclically

during time periods, said voltage applied during odd numbered time periods between the cathodes alternately and the pairs of pins alternately, the cathodes being negative during said odd numbered cycles, said voltage being applied during even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

7. A method of treating a bone fracture comprising the steps of:

(a) fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site;

(b) fixing at least one cathode with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and

(c) applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between a cathode and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

7. A method of treating a bone fracture comprising the steps of:

(a) fixing the site of the bone fracture with an

external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site;

(b) fixing a plurality of cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and

(c) applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between the cathodes alternately and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

8. A method of treating a bone fracture comprising the steps of:

(a) fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site;

(b) fixing at least four cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and

(c) applying a voltage cyclically during odd numbered and even numbered time periods, applying said voltage during odd numbered time periods between the cathodes

alternately and the pairs of pins alternately, the cathode being negative during said odd numbered cycles, applying said voltage during even numbered time periods between the pairs of pins alternately, the polarity being reversed between said pins during alternate even numbered time periods.

9. A method of treating a bone fracture comprising the steps of:

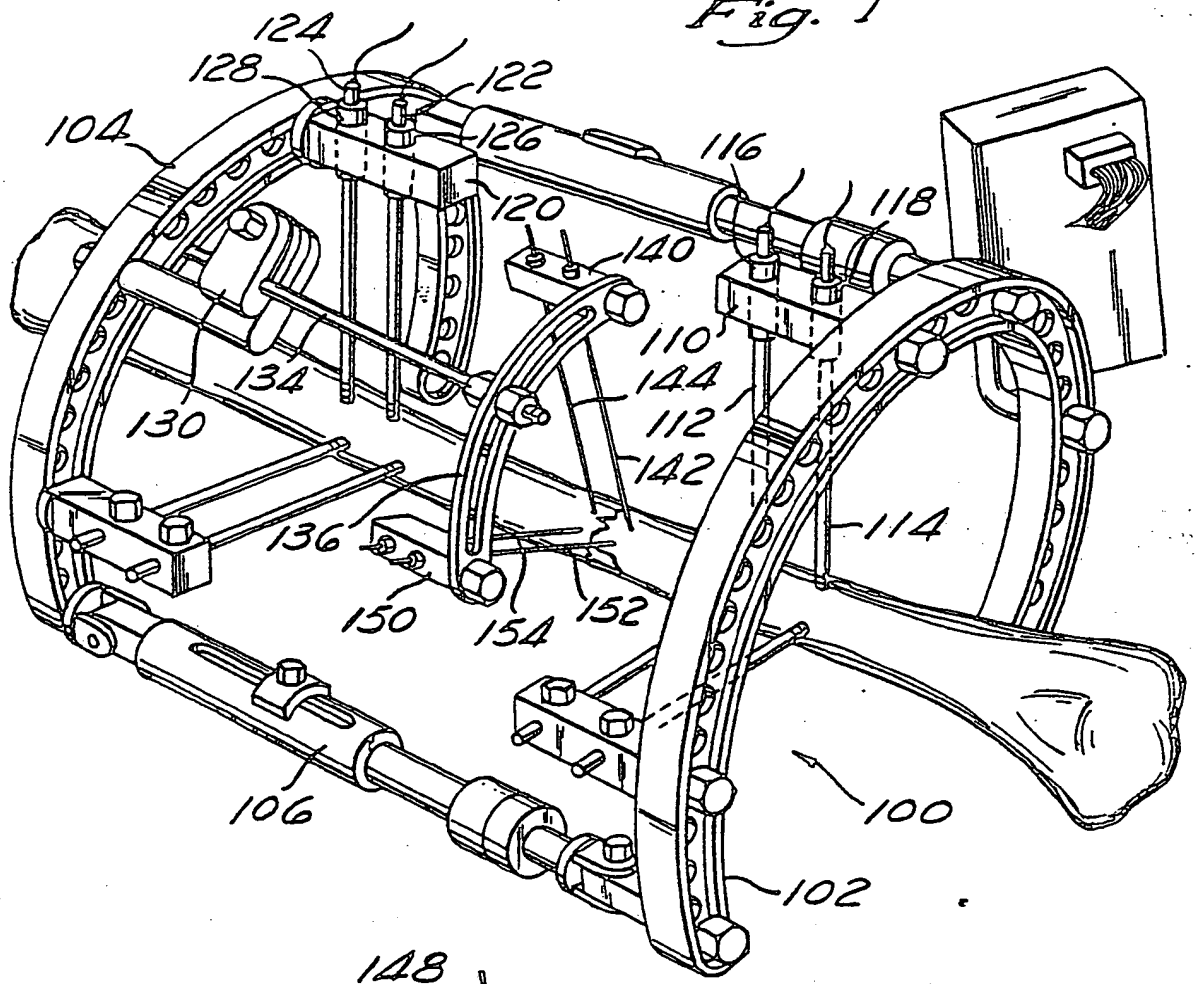
(a) fixing the site of the bone fracture with an external fixation device, including inserting a first pair of fixation pins one on each side of said site, and inserting a second pair of fixation pins one on each side of side site;

(b) fixing at least four cathodes with the distal end thereof in electrical contact with the bone adjacent the fracture site therein; and

(c) applying a voltage cyclically during odd numbered and even numbered time periods, the cathodes at all times having either no voltage or negative voltage applied thereto, the pins having either positive, negative or no voltage applied thereto, either the first pins or the second pins being positive when a negative voltage is applied to any cathode, the voltage application being cycled to cause electron flow from a first cathode to the first pins in a first period, from the first pins to the second pins during a second period, from the second cathode to the second pins in third period, from the second pins to the first pins in fourth period, from the third cathode to the first pins in the fifth

period, from the first pins to the second pins in the sixth period, from the fourth cathode to the second pins in the seventh period, and from the second pins to the first pins in the eighth period.

Fig. 1



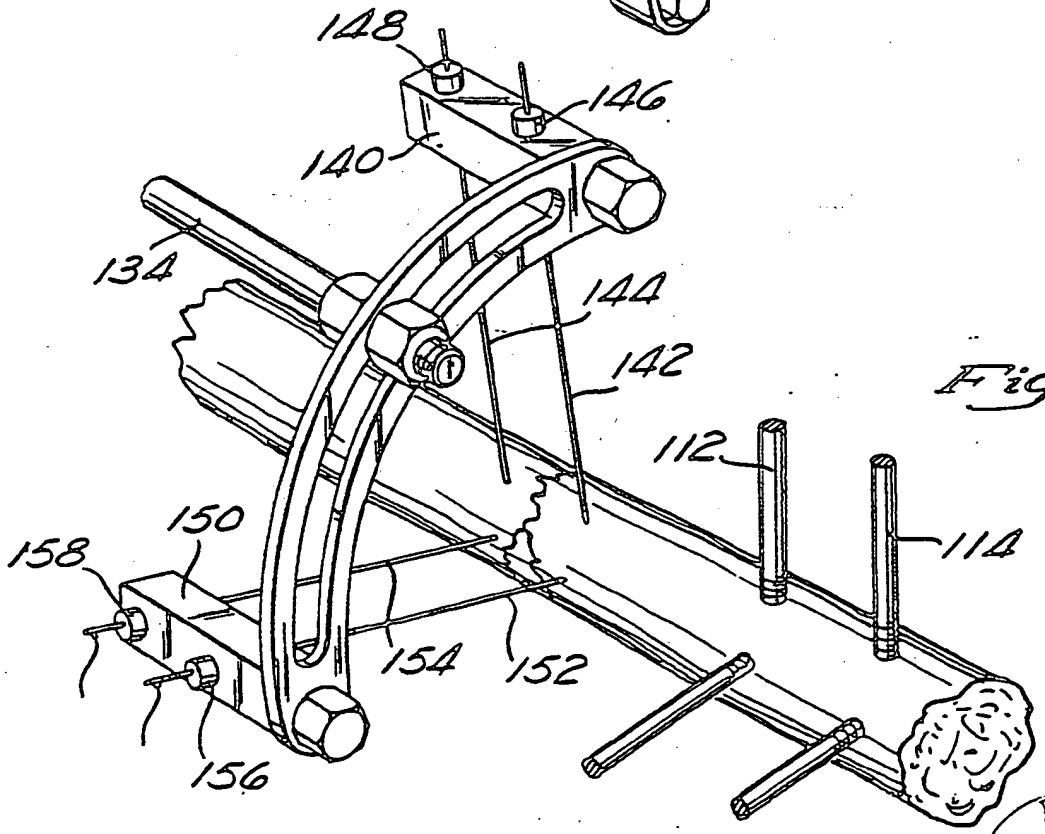


Fig. 2

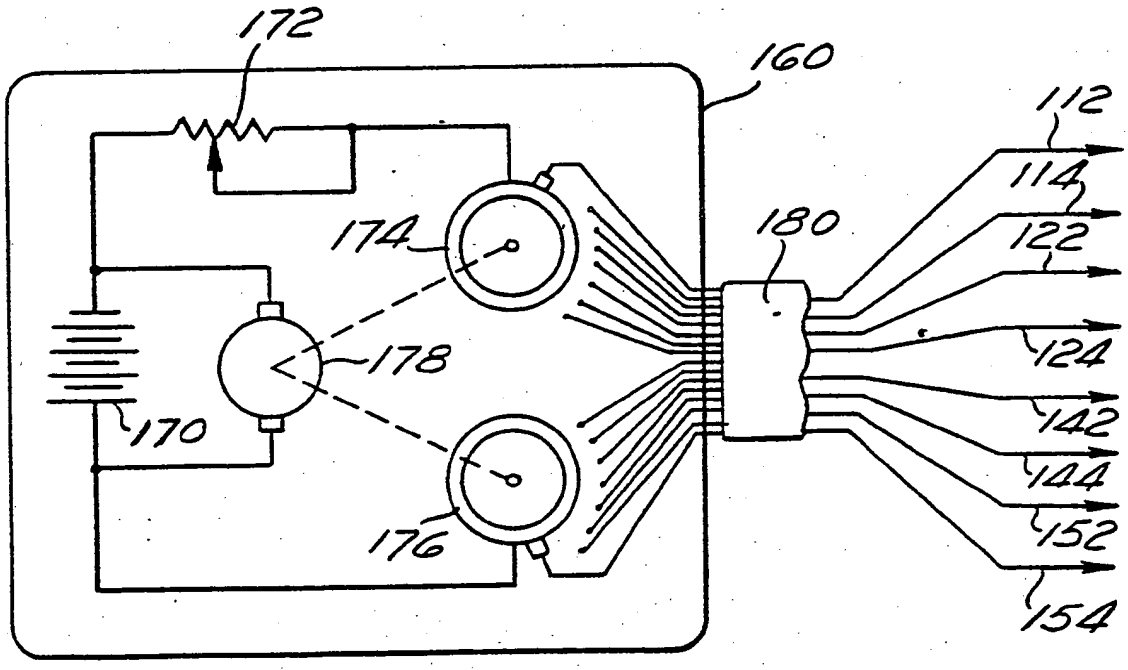


Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00167

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61N 1/18
US Cl 128/419F

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/92A, 92G, 419F, 421-3

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
Y	US, A, 4,365,624	28 December 1982 JAQUET	1, 4-9
Y	US, A, 4,308,863	05 January 1982 FISCHER	1, 4-9
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* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [3]	Date of Mailing of this International Search Report [3]
29 March 1984	11 APR 1984
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	

Form PCT/ISA/210 (second sheet) (October 1981)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
Y	N "The Alternate Treatment of Fracture Nonunion", issued September, 1979, Zimmer USA, Lit. No. B-2360-1	1-9